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Antimicrobials Division
EPA/OPP MICROBIOLOGY LABORATORY
ESC, Ft. Meade, MD

Standard Operating Procedure
for
Disinfectant Sample Login and Tracking

SOP Number: COC-01-03

U.S. Environmental Protection Agency

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ESC, Ft. Meade, MD

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for
Disinfectant Sample Login and Tracking

SOP Number: COC-01-03

Date Revised: 11-26-05

Initiated By: _____ Date: ____/____/____

Print Name: _____

Technical Review: _____ Date: ____/____/____

Print Name: _____

Technical Staff

QA Review: _____ Date: ____/____/____

Print Name: _____

QA Officer

Approved By: _____ Date: ____/____/____

Print Name: _____

Branch Chief

Effective Date: ____/____/____

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1.0 SCOPE AND APPLICATION:

- 1.1 This protocol describes procedures used to ensure appropriate login and tracking of disinfectant samples. Documenting the receipt, storage, handling, use, and disposal of product samples is essential. Various chain-of-custody forms are used to document the movement of all product samples from sample collection through disposal.

2.0 DEFINITIONS: None

3.0 HEALTH AND SAFETY:

- 3.1 Follow precautions for storage and handling as stipulated by the product manufacturer.
- 3.2 Flammable samples are stored in the locked flammable storage cabinets.

4.0 CAUTIONS:

- 4.1 Condition of the primary shipping container, the product sample, and the chain-of-custody seal must be noted on the appropriate form.
- 4.2 Samples should be logged in and transferred to the storage facility as soon as possible by an official OPP Microbiology Laboratory sample custodian. Sample custodians are responsible for signing out samples for testing and returning the samples to the storage area following procedures outlined in this SOP.

5.0 INTERFERENCES:

- 5.1 Insufficient chain-of-custody documentation, illegible entries by the inspectors, or incorrect entries of sample identity by the inspectors may interfere with completion of the sample login process. Illegible, missing, or incorrect entries that may interfere with the completion of the sample login process are addressed by contacting the inspector for clarification. Deficiencies are documented. A written explanation by the inspector may be required.
- 5.2 Samples which arrive in poor condition will not be accepted for analysis. The contents will be discarded and the inspector and the Office of Enforcement and Compliance Assurance (OECA) will be notified to send replacement samples.

6.0 PERSONNEL QUALIFICATIONS:

- 6.1 Sample custodians for the laboratory have been identified in Section 10.2 below. Sample custodians have received appropriate training from the team leader on chain-of-custody procedures.
- 6.2 Personnel are required to be knowledgeable of the procedures in this SOP. Documentation of training and familiarization with this SOP can be found in the training file for each employee.

7.0 SPECIAL APPARATUS AND MATERIALS:

- 7.1 Rooms B204 and D204 at EPA's Environmental Science Center have been designated as the secured storage sites for product samples. Flammable samples are stored in the locked flammable storage cabinets in room B204. All other samples are stored in room D204. The temperature and relative humidity of sample storage rooms will be recorded once daily each working day (Monday through Friday excluding holidays and days when the ESC is closed for any reason) on the appropriate Temperature Record form (see SOP QC-08, Temperature/Humidity of the Sample Storage Room).

8.0 INSTRUMENT OR METHOD CALIBRATION: Not applicable

9.0 SAMPLE HANDLING AND STORAGE:

- 9.1 Product samples will be handled and maintained for testing per the conditions outlined below in the "Procedure and Analysis" section.

10.0 PROCEDURE AND ANALYSIS:

- 10.1 Product samples are shipped to the lab to the attention of Dr. Stephen Tomasino, USEPA, Environmental Science Center (ESC), 701 Mapes Road, Ft. Meade, MD 20755-5350.
- 10.2 Upon arrival at the ESC loading dock, loading dock personnel are required to contact a sample custodian who will receive the samples and initiate the Shipping and Receiving Record for Disinfectant Products (see 16.1). Loading dock personnel are required to fill in several fields of this form. In addition, the loading dock personnel or sample custodian will record a number on each primary shipping container (usually a box) to indicate the number of containers received as follows:

Container #__ of __/Initials

Sample custodians for the OPP Microbiology Laboratory are: Stephen Tomasino, Michele Cottrill, Marc Rindal, Kiran Verma, Rebecca Schultheiss, Luisa Samalot-Gaud, Rebecca Fiumara, and Mick Yanchulis. Sample custodians are authorized to accept, place, and remove samples from the sample storage area, record chain-of-custody information, prepare product dilutions, and return samples to the storage area.

- 10.3 Each shipping container is inspected by a sample custodian for external structural damage, tampering, and evidence of leaks or spills. Any sign of damage, tampering, or leaks or spills is documented on the Shipping and Receiving Record for Disinfectant Products (see 16.1) and any chain-of-custody forms provided by the inspector.
- 10.4 The shipping container is opened and the contents are inspected. The plastic bag and the chain-of-custody seals are closely inspected for damage or signs of tampering. Individual samples are inspected for leakage or damage by a sample custodian. The sample custodian will review the chain-of-custody documentation sent by the inspector, and if necessary apply signature and date of receipt. The sample custodian will review all paperwork sent by the inspector to identify any pertinent information such as lot number, sample expiration date, storage conditions, etc. Then, the sample custodian will initiate a History of Official Sample Form (EPA Form 3540-17) (see 16.2).
 - 10.4.1 Correct and complete entry of information on the History of Official Sample Form is an essential component to the chain-of-custody documentation. One form is used per unique product sample number. The sample custodian who received the shipment may request another sample custodian to complete the History of Official Sample Form, as long as the sample custodian completing the Form performs the actual inspection of the shipping container and sample. For clarification purposes, follow the guidance for data entry for the specified fields listed below; fields #1-#4 are self-explanatory:
 - 10.4.1.1 #5. DATE RECEIVED: Enter the date the shipment was received by the laboratory. This date will be the same as the date entered on the Shipping and Receiving Record for Disinfectant Products.
 - 10.4.1.2 #6. RECEIVED BY: The signature of the sample custodian

responsible for receiving the shipment from the loading dock personnel is required; date of signature is also required. The sample custodian signing as the sample receiver may not be the individual who completes the History of Official Sample Form.

- 10.4.1.3 #7. RECEIVED FROM: Record the name of the ESC loading dock personnel and the person who actually shipped the package to the ESC (inspector, administrative assistant).
- 10.4.1.4 #8. SENT VIA: Enter the name of the shipping company and type of delivery.
- 10.4.1.5 #9. SAMPLE CONDITION: Record as Good or Poor; if Poor, describe the condition in detail in #26 REMARKS.
- 10.4.1.6 #10. CONDITION OF SEALS: Record as Good or Poor; if Poor, describe the condition in detail in #26 REMARKS.
- 10.4.1.7 #11. SEALED BY: Enter the name which appears on the seals (the name should also appear on inspector's chain-of-custody paperwork).
- 10.4.1.8 #12. DATE SEALED: Enter the date taken from the seals (the date should also appear on the inspector's chain-of-custody paperwork).
- 10.4.1.8 #13. PIECES RECEIVED: Enter the number of seals and the number and type of product containers per seal.
- 10.4.1.9 #14. PLACED STORED: Enter the official sample storage room (B204 or D204).
- 10.4.1.10 Fields #15-#24 should be used if samples are relocated.
- 10.4.1.11 #26. REMARKS: Record notable items such as damaged samples, labeling clarification, name of the sample custodian completing the History of Official Sample Form (if different from the individual in #6), and lot number. (Note: Record lot number on the History of Official Sample Form only if the inspector has recorded a lot number on his

paperwork. Do not assume that codes imprinted on containers are lot numbers. If the inspector failed to record a lot number on his paperwork, the sample lot number will be considered to be unknown.)

- 10.5 Sample collection and chain-of-custody information will be maintained in the Disinfectant Product Field Chain-of-Custody Documentation from Inspector notebook. Deficiencies in paperwork accompanying the shipment (i.e. lack of field chain-of-custody papers) are documented.
- 10.6 Prior to testing, a sample custodian initiates a Laboratory Chain-of-Custody Form (see 16.3) and a Chain-of Custody Seal Log (see 16.4) for each product sample received.
- 10.7 The Laboratory Chain-of-Custody Form is filled out whenever a product sample is removed from storage.
- 10.8 Prior to completion of the draft performance report, the product label will be photocopied or photographed directly from a product container; a copy will be filed in the Disinfectant Product Field Chain-of-Custody Documentation from Inspector notebook. In addition, sample numbers found on the product containers will be photocopied; copies will be filed in the Disinfectant Product Field Chain-of-Custody Documentation from Inspector notebook.
- 10.9 Broken chain-of-custody seals are retained on a Chain-of-Custody Seal Log (see 16.4). A new chain-of-custody seal will be established on the sample as per the directions in the Pesticides Inspection Manual (see ref. 15.1).
- 11.0 DATA ANALYSIS/CALCULATIONS: None
- 12.0 DATA MANAGEMENT/RECORDS MANAGEMENT:
 - 12.1 Data will be recorded promptly, legibly, and in indelible ink on the Shipping and Receiving Record for Disinfectant Products, History of Official Sample Form (EPA Form 3540-17), Laboratory Chain-of-Custody Form and a Chain-of Custody Seal Log forms. Completed forms are archived in notebooks kept in secured file cabinets in room D217. Only authorized personnel have access to the secured files. Archived data is subject to OPP's official retention schedule contained in SOP ADM-03, Records and Archives.

13.0 QUALITY CONTROL:

- 13.1 Timely, accurate, and legible sample information recorded in ink is required on all chain-of-custody documentation.
- 13.2 For quality control purposes, the required information is documented on the appropriate forms (see 16.0).

14.0 NONCONFORMANCE AND CORRECTIVE ACTION:

- 14.1 Any deviation from the protocol will be documented.

15.0 REFERENCES:

- 15.1 Pesticides Inspection Manual (Chapter 11) 1989.

16.0 FORMS AND DATA SHEETS

- 16.1 Shipping and Receiving Record for Disinfectant Product Sample Form
- 16.2 History of Official Sample Form (EPA Form 3540-17)
- 16.3 Laboratory Chain-of-Custody Form
- 16.4 Chain-of Custody Seal Log

Shipping and Receiving Record for Disinfectant Product Samples Form
OPP Microbiology Laboratory

Shipping and Receiving Record for Disinfectant Product Samples	
<u>Loading Dock Personnel</u> (Date/Initials): _____ Shipping Container # ____ of ____ Date and Time Received: _____ Received By: _____ Received From: _____ Type of Delivery: _____ Tracking Number (if available): _____ _____	<u>Loading Dock Personnel</u> (Date/Initials): _____ Shipping Container # ____ of ____ Date and Time Received: _____ Received By: _____ Received From: _____ Type of Delivery: _____ Tracking Number (if available): _____ _____
<u>Sample Custodian</u> (Date/Initials): _____ Condition of Primary Shipping Container: _____ Product Name(s): _____ _____ EPA Reg. No.(s): _____ _____ Sample Numbers: _____ _____ _____ _____	<u>Sample Custodian</u> (Date/Initials): _____ Condition of Primary Shipping Container: _____ Product Name(s): _____ _____ EPA Reg. No.(s): _____ _____ Sample Numbers: _____ _____ _____ _____

History of Official Sample Form (EPA Form 3540-17)

HISTORY OF OFFICIAL SAMPLE		1. SAMPLE NUMBER	2. REGISTRATION NUMBER
		3. PRODUCT	
4. LABORATORY			
5. DATE RECEIVED			
6. RECEIVED BY			
7. RECEIVED FROM			
8. SENT VIA			
9. SAMPLE CONDITION			
10. CONDITION OF SEALS			
11. SEALED BY			
12. DATE SEALED			
13. PIECES RECEIVED			
14. PLACE STORED			
15. ASSIGNED BY			
16. ASSIGNED TO			
17. DELIVERED BY			
18. DATE DELIVERED			
19. NUMBER SUBS RECEIVED			
20. SUBS ANALYZED			
21. DATE SEAL BROKEN			
22. DATE RESEALED			
23. RESEALED BY			
24. PLACE STORED			
25. DATE JACKET SENT OUT			
26. REMARKS			

Laboratory Chain-of-Custody Form

OPP Microbiology Laboratory

[illegible]

Chain-of-Custody Seal Log
OPP Microbiology Laboratory

Chain-of-Custody Seal Log	
<u>Product Information:</u> Product EPA Reg. #: _____ Product Name: _____ Sample #: _____ Date Product Received: ____/____/____	
Date/Initials	Apply Seals Below (1 seal per row)